

## **REMARKS**

### **I. Status of the Claims**

Claims 1-10, 12-21, and 31-37 were pending under examination. Claims 11 and 22-30 were previously canceled. The Examiner has indicated the allowability of claims 1-9 and 31-36.

Claims 16 and 17 have also been held allowable if rewritten in independent form. Upon entry of the present amendment, claim 16 is canceled. Independent claim 12 is amended to recite the limitation of claim 16 and therefore identical to claim 16 before its cancellation. Claim 17 is rewritten to adopt the format of an independent claim.

New claims 38-43 are added as dependent claims as amended claim 17. These new claims correspond to claims 13-15 and 18-20 (which depend from claim 12), respectively. Claim 37 is amended to replace the word "method" with "culture" to ensure proper antecedent basis. The present amendment introduces no new matter and requires no additional searches. Its entry is respectfully requested.

### **II. Objection to the Specification**

The Examiner objected to the specification for several informalities including omission of U.S. Patent No. for USSN 09/522,376, and inconsistencies between the figures and the description of the figures. Upon entry of the present amendment, the specification is cured of these defects.

### **III. Claim Rejections**

#### **A. 35 U.S.C. §112, Second Paragraph**

Claims 37 was rejected in the final Office Action under 35 U.S.C. §112, second paragraph, for alleged indefiniteness. Specifically, the Examiner stated that the language "the method of claim 17" lacks proper antecedent basis. Accordingly, claim 37 has been amended to replace the word "method" with "culture." Applicants submit that this rejection is overcome.

B. 35 U.S.C. §112, First Paragraph

Claims 10 and 21 remained rejected under 35 U.S.C. §112, first paragraph, for alleged lack of enablement. Specifically, the Examiner stated that the declaration under 37 C.F.R. §1.132 filed during prosecution of USSN 09/522,376 (now U.S. Patent No. 6,448,045) is insufficient to overcome the enablement rejection, because a patent issued from the present application would have a term different from that of U.S. Patent No. 6,448,045. In response, Applicants hereby submit a new declaration by inventor Dr. Fred Levine regarding the  $\beta$ lox5 cell line. The withdrawal of the enablement rejection is respectfully requested.

C. 35 U.S.C. §102 and 35 U.S.C. §103

Claims 12-15 remained rejected under 35 U.S.C. §102(b) for alleged anticipation by Egan *et al.* Claims 18 and 19 remained rejected under 35 U.S.C. §103(a) for alleged obviousness over Egan *et al.* in view of Levine *et al.* Applicants respectfully traverse the rejections in light of the present amendment. As amended, claim 12 is equivalent to claim 16, which is now canceled, in the independent form. Since the Examiner has indicated in the final Office Action that claim 16 would be allowable except for its dependent form, Applicants surmise that claim 12 as well as its dependent claims 13-15 and 18-21 are now also allowable.

Applicants respectfully request the withdrawal of the anticipation rejection and obviousness rejection.

Appl. No. 10/041,845  
Amdt. dated July 27, 2004  
Amendment under 37 CFR 1.116 Expedited Procedure  
Examining Group

PATENT

**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

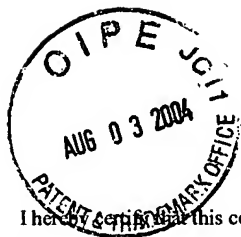
If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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Reg. No. 54,111

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Attachments (Declaration of Fred Levine under 37 C.F.R. §1.132)  
60260596 v1



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PATENT  
Attorney Docket No.: 023070-110910US  
Client Ref. No.: 2001-309-1

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

On July 30, 2004

TOWNSEND and TOWNSEND and CREW LLP

By: Karen Karlin

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

Pamela Itkin-Ansari  
Dominique Dufayet de la Tour  
Fred Levine

Application No.: 10/041,845

Filed: October 18, 2001

For: INDUCTION OF BETA CELL  
DIFFERENTIATION IN HUMAN  
CELLS

Customer No.: 20350

Confirmation No. 7736

Examiner: David A. Lambertson

Technology Center/Art Unit: 1636

DECLARATION OF FRED LEVINE

UNDER 37 C.F.R. § 1.132

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

I, Fred Levine, being duly warned that willful false statements and the like are punishable by fine or imprisonment or both (18 U.S.C. § 1001), and may jeopardize the validity of the patent application or any patent issuing thereon, state and declare as follows:

1. All statements herein made of my own knowledge are true, and statements made on information or belief are believed to be true and correct.

2. I am a named inventor on the above-referenced patent application and have control over the conditions of the deposit described herein.

3. I certify that:

(a) The  $\beta$ lox5 cell line was deposited on July 19, 2001, with American Type Culture Collection (ATCC), 10801 University Blvd., Manassas, VA 20110-2209, and granted Accession number ATCC PTA-3532. The deposit was made pursuant to the provisions of the Budapest Treaty. The deposited material is the same as that identified in the specification.

(b) All restrictions, except those required by law or regulation for safety, health, or similar reasons, on the availability to the public of the cell lines identified in Paragraph (a) will be irrevocably removed upon the granting of a patent for the above-identified application. Access to the deposits will be available during pendency of the application to one determined by the Commissioner to be entered thereto under 37 CFR §1.14 and under 35 USC §122.

(c) The cell line identified in Paragraph (a) above will be maintained at the ATCC and replaced in the event of mutation, nonviability, or destruction for a period of at least five (5) years after the most recent request for release of a sample was received by ATCC, for a period of at least thirty (30) years after the date of deposit, or during the enforceable life of the related patent, which period is longest.

Date:

July 15, 2004

By:

Fred Levine

Fred Levine